"DIAGNOSTIC CATHETER AND ITS METHOD OF APPLICATION"

BACKGROUND OF THE INVENTION

The present invention relates to a catheter for medical use.

In particular, the present invention relates to a diagnostic catheter suitable for perfusing a substance, such as for example a contrast liquid, in blood vessels.

In the medical field, in particular in cardiac surgery, coronary by-pass intervention is very widespread, consisting, as the name indicates, in constructing "bridges" capable of passing over the coronary stenoses responsible for cardiac ischemia. As ducts for the by-passes, the internal mammary arteries (dx and sx) are by far preferred by surgeons for the greater viability of the intervention over the years. The right mammary artery is often anastomosed to the left in a "Y" so as to be able to reach with it all the vessels of the posterior surface of the heart. In order to be able to carry out such interventions it would be ideal to be able to verify in advance the calibre, length and viability of the vessels to be anastomosed. Catheters are known in the art which are suitable for infusing a contrast liquid into a vessel in such a way as to verify its anatomical characteristics (calibre and

length) in advance.

Such techniques, defined as direct selective infusion, consist in directly selecting the vessel to be infused, by means of a catheter. They therefore involve the need to span with the catheter a main vessel from which branches off the vessel to be infused, and to enter the bifurcation with the catheter in order to be able to inject the substance directly into the preselected vessel.

These known catheters have extremely soft and flexible ends which have the task of adapting to the curvatures of the vessels to enter them.

Sometimes these catheters have the drawback of dissecting the vessels, in particular vessels of reduced calibre or having accentuated curvatures at the branchings from which they start. The lesions caused by incorrect insertion of a catheter may be extremely serious, so that such a known technique is not used for vessels having the above-mentioned characteristics.

It is known from US 5908407 and US 6558401 B1, to provide catheters comprising occluding means both upstream and downstream an aperture to deliver a fluid in a selected vein. These known catheters are not able to perfuse small quantities of a liquid directly in a target vein.

SUMMARY OF THE INVENTION

The problem underlying the present invention is that of providing a catheter which solves the drawbacks cited with reference to the prior art.

Such drawbacks and limitations are solved effectively by a catheter according to claim 1.

Other embodiments of the catheter according to the invention are described in the subsequent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Further characteristics and advantages of the invention in question will become clearer from the following description of some of its preferred and non-limiting exemplary embodiments, in which:

Figure 1 shows a side view in section of a catheter according to one embodiment of the invention, in a non-operative state;

Figure 2 shows a side view in section of the catheter of Figure 1 in an operative state;

Figure 3 shows a side view in section of the catheter of Figure 1, inserted into a vessel and in an operative state;

Figures 4A-4D show side views of occluding bodies according to different embodiments of the invention;

Figure 5 shows a sectional view of a catheter

according to a further embodiment of the invention;

Figure 6 shows a sectional view of a catheter according to a further embodiment of the invention;

Figure 7 shows a sectional view of the catheter of Figure 1 along the line VII-VII of Figure 1;

Figure 8 shows a diagrammatic view illustrating an application of said catheter within a subclavian artery for infusing a liquid in a mammary artery; and

Figure 9 shows an enlarged detail of Figure 8.

DETAILED DESCRIPTION OF THE INVENTION

Elements or parts of elements common to the embodiments described hereinafter will be indicated by the same numerical references.

With reference to the aforesaid figures, the reference 4 indicates generally a catheter for medical use according to the invention, suitable for being inserted into a duct 5 comprising a first blood vessel 6, for example an artery, and a second blood vessel 7 which branches off from the first vessel 6 at a bifurcation 8, in order to perfuse a substance from the first vessel 6 to the second vessel 7, without cannulating the second vessel 7.

By the term first vessel there is to be understood the vessel cannulated directly by the catheter 4 and from

which starts or branches off the second vessel 7, in which it is desired to infuse a substance.

This definition makes no reference to the function or to the characteristics which said vessels have within the circulatory system, so that the first vessel 6 is the vessel to be cannulated and the second vessel 7 is the vessel to be perfused indirectly, or without direct insertion of the catheter 4.

The catheter 4 comprises a catheter body 10, having a substantially tubular shape, which extends from a proximal end 12 to a distal end 16, along a main axis of extension X.

The catheter body 10 comprises a main cavity 20 which passes through it between the proximal end 12 and the distal end 16 and preferably having a circular cross-section.

The main cavity 20 is suitable for receiving a guide cable, not shown, for the insertion of the catheter 4.

In an intermediate position between the proximal end 12 and the distal end 16, preferably in proximity to the distal end 16, the catheter body 10 comprises at least one opening 24, preferably a plurality of openings, suitable for perfusing a substance and passing through a lateral wall 28 of the catheter body 10, so as to place the main cavity 20 in fluid communication with the

surroundings into which the catheter 4 is being introduced, for example with the cavity of the first vessel 6 bounded by an inner wall 32 of said first vessel 6.

The openings 24, as shown for example in Figures 1-3, are not aligned with one another but are preferably disposed in a helical direction with respect to the axis X.

Advantageously, said openings 24 are of such dimensions that the sum of the areas of the openings 24 is not less than the area of the main cavity 20 of the catheter body 10 at the distal end 16.

According to a preferred embodiment, the catheter body 10 comprises a secondary cavity 36 which passes through the catheter body 10 from the proximal end 12 to the distal end 16, extending, for example, parallel to the main cavity 20.

The secondary cavity 36 is fluidly separated from the main cavity 20, or the two cavities, main and secondary 20, 36, are not in fluid communication with each other.

Preferably, the second cavity 36 is provided in a thickness of the lateral wall 28 of the catheter body 10.

As emphasized in Figure 7, the catheter body 10 preferably has an oval, or substantially elliptical

cross-section, having a first pole 37' more pronounced than a second pole 37" diametrically opposed to the first pole 37'. At the first pole 37', the thickness of the lateral wall 28 of the catheter body is slightly greater so as to receive the secondary cavity 36.

Preferably, the secondary cavity 36, at the distal end 16, opens externally of the catheter body 10; for example, it opens into a lateral hole 38 located on the lateral wall 28 of the body itself.

Preferably, the lateral hole 38 is positioned along the catheter body 10 between the plurality of openings 24 and the distal end 16.

The catheter body 10, at the distal end 16, comprises a main aperture 42 into which opens the main cavity 20 having, according to one embodiment, a calibre substantially similar to the median calibre of the catheter body 10.

According to one embodiment, illustrated for example in Figure 6, the catheter body 10, at the distal end 16, has a portion with tapered profile 46, for example a frustoconical profile, such that the calibre of the main aperture 42 is less than the median calibre of the catheter body 10.

The calibre of the main aperture 42 is however such as to allow the passage of a guide cable for the

insertion of the catheter 4 into a vessel.

The catheter 4 comprises first occluding means 60 and second occluding means 62, in which the first occluding means 60 are suitable for at least partially occluding a gap 63 between the catheter body 10 and the first vessel 6 into which the catheter 4 is inserted, and the second occluding means 62 can be associated internally with the main cavity 20 and suitable for at least partially occluding said main cavity 20 of the catheter body 10.

The first and second occluding means 60, 62 define a preferred direction of outflow of a fluid from the main cavity 20 of the catheter body 10 through the openings 24 and, advantageously, from the openings 24 to the second vessel 7 which branches off from the first vessel 6.

In other words, the first and second occluding means 60, 62 co-operate with one another to create a resistance to the passage of fluid beyond the distal end, favouring the outflow of fluid through said openings 24, so as to perfuse the fluid indirectly into the second vessel 7, avoiding the dispersion of fluid in the first vessel 6.

In yet other words, the first and second occluding means 60, 62, at a portion of the catheter body 10 comprised between the openings 24 and the distal end 16, substantially effect the occlusion of the cavity of the

first vessel 6 into which the catheter 4 is inserted so as to oppose a flow of fluid in the direction of the axis X through the distal end 16 and direct a flow of fluid from the openings 24 of the catheter body 10 towards the second vessel 7.

The first occluding means 60, as illustrated for example in Figure 3, comprise an inflatable element 64, positioned round the lateral wall 28 of the catheter body 10 and advantageously in fluid connection with the lateral hole 38 of the secondary cavity 36, so as to be able to be actuated from the proximal end 12 through the secondary cavity 36.

The inflatable element 64 in a non-operative state, illustrated for example in Figure 1, adheres substantially to the lateral wall 28 of the catheter body 10, while in an operative or working state, illustrated for example in Figure 2, in which it fills with a substance injected for example through the secondary cavity 36, the inflatable element 64 expands so as to be substantially in contact with the inner wall 32 of the first vessel 6. In other words, the inflatable element 64, in a working state, tends to occupy the substantially toroidal gap 63 comprised between the lateral wall 28 of the catheter body 10 and the inner wall 32 of the first vessel 6 into which the catheter is inserted.

The second occluding means 62 comprise an occluding body 68, suitable for being introduced into the main cavity 20, and an insertion cable 72 for insertion of the occluding body 68, firmly connected to the occluding body 68, suitable for allowing the insertion and positioning of the occluding body 68 into the main cavity 20.

According to one embodiment, shown for example in Figure 4A, the occluding body 68 is substantially spherical in shape, such that a diameter of the occluding body is smaller than the calibre of the main cavity 20.

According to a further embodiment, shown in Figure 4B, the occluding body 68 is of frustoconical shape, having a major base and a minor base, such that, following the insertion of the occluding body 68 into the main cavity 20, the minor base faces towards the distal end 16 and the major base faces towards the proximal end 12.

According to a further embodiment, shown in Figure 4C, the occluding body 68 has a rhomboidal or lozenge shape, having a main axis of symmetry R which, in a configuration of mounting of the occluding body 68 in the catheter body 10, is disposed substantially parallel to the axis X.

According to a further embodiment, shown for example in Figure 4D, the occluding body 68 comprises a membrane

76 positioned at the distal end 16. The membrane 76 is disc-shaped and is suitable for at least partially occluding the main cavity of the catheter body 10.

According to a further embodiment, shown in Figure 5, the membrane 76 is not connected to the insertion cable but is firmly fixed to the distal end 16 of the catheter body 10, so as to cap the main aperture 42. Preferably, the membrane 76 is disc-shaped, with a diameter substantially equal to the cavity of the distal end 16 and has a hole 80 suitable for allowing the passage of the guide cable of the catheter 4.

Preferably, this membrane 76 is of elastic material, so that the hole 80 which it has for the passage of the guide cable tends to close following the withdrawal of the cable itself.

The insertion cable 72 has a thickness less than the calibre of the main cavity 20 and, at one of its attachment ends 84, is connected to the occluding body 68.

Preferably, the insertion cable 72, at a fixing end 88 opposed to said attachment end 84, comprises threaded connection means 92, suitable for producing a threaded connection with a corresponding threaded portion of the catheter body 10 so as to effect the locking of the occluding body 68 within the main cavity 20.

Preferably, the insertion cable 72 has a length such that, following the insertion of the second occluding means 62 into the main cavity 20 and the relevant fixing to the catheter body 10, the occluding body 68 is positioned at a point comprised between the openings 24 and the distal end 16.

At the proximal end 12, the catheter body 10, as illustrated for example in Figure 3, comprises a main pathway 96 fluidly connected to the main cavity 20. Preferably, the main pathway 96 is coaxial with the main cavity 20 and has an internal calibre not less than the internal calibre of the main cavity 20.

By internal calibre of a cavity, there is to be understood the inside diameter of the cavity having a substantially cylindrical shape.

The main pathway 96 is suitable for receiving within it the guide cable for the insertion of the catheter, not shown.

The main pathway 96 is also suitable for receiving an occluding body to allow its introduction and positioning within the main cavity 20.

Preferably, the main pathway 96 comprises a threaded section 100 at a free end 104 thereof, said threaded section 100 being capable of engaging with the threaded connection means 92 of the second occluding means 62.

At the proximal end 12 the catheter body comprises a secondary pathway 108, hermetically separated from the main pathway 96 and fluidly connected to the secondary cavity 36, the secondary pathway 108 being suitable for receiving a fluid at the inlet and conveying it by means of the secondary cavity 36 to the first occluding means 60 to allow the actuation thereof.

For example, the secondary pathway 108 is suitable for being connected to a system for controlling the introduction of a fluid, comprising for example a tap (not shown), so as to be able to control and measure out the quantity of fluid introduced into the secondary cavity 36 and therefore the actuation of the first occluding means 60.

The catheter body 10, at the proximal end 12, further comprises an infusion pathway 112 which opens into the main cavity 20 and is suitable for receiving at the inlet a substance to be perfused and for directing it into the main cavity 20.

Preferably, the infusion pathway 112 comprises a threaded portion capable of being connected to means suitable for the controlled release of a substance, such as, for example, a contrast liquid.

A description will now be given of the technique to be used for perfusing a substance in a vessel through the

catheter described above.

The technique consists in making a percutaneous puncture in a main or first vessel 6, for example a femoral artery, with a metal needle of dimensions such as to permit the passage of the guide cable for the catheter 4.

The guide cable is then introduced, bringing it at least as far as the branching or bifurcation 8 from which starts the secondary vessel 7 in which it is intended to perfuse a liquid, and the needle is withdrawn.

On the guide cable there is positioned a catheter introducer, typically for angiography catheters, using suitable dilators of increasing dimensions, and the catheter 4 is introduced and is pushed far enough to pass beyond, for example by three or four centimetres, the start of the second vessel 7 to be injected.

The contrast fluid is then injected as a preliminary, in order to evaluate the calibre of the main vessel, so as to establish the magnitude of the following inflation of the inflatable element 64, and the guide cable is withdrawn completely.

The occluding body 68 is introduced, effecting the positioning thereof for example by means of screwing home the threaded connection means 92 onto the corresponding main pathway 96.

Advantageously, the positioning of the occluding body 68 is effected in a portion comprised between the openings 24 and the distal end 16, so as to occlude or sub-occlude the main cavity 20.

The inflatable element 64 is then inflated, by injecting a predetermined quantity of liquid into the secondary cavity to inflate the inflatable element 64 such that the latter comes into contact with the inner wall 32 of the first vessel 7 and it occludes or sub-occludes the gap 63.

It is then possible to inject the substance to be perfused, for example a contrast liquid, through the infusion pathway 112 which opens into the main cavity 20. The liquid which flows from the proximal end 12 to the distal end 16 encounters a resistance to its passage, owing to the first and second occluding means which substantially limit any blow-by beyond the distal end through the main aperture 42; the liquid injected then flows down through the plurality of openings 24 suitably disposed at the bifurcation 8 from which starts the second vessel 7 to be perfused.

As can be understood from what has been described, the catheter according to the invention makes it possible to overcome the drawbacks exhibited by the catheters of the prior art.

Advantageously, the catheter described makes it possible also to select vessels of small calibre, avoiding cannulating them directly and therefore without running the risk of damaging them, for example dissecting them.

The catheter described therefore makes it possible to carry out investigations on blood vessels in a substantially non-traumatic manner for the latter, in so far as direct cannulation thereof is avoided.

For example, such a solution makes it possible to select the mammary artery indirectly from its point of origin from the subclavian artery. This is useful pre-operatively, since it makes it possible to verify the quality of the mammary arteries and the feasibility of a "Y" anastomosis intervention between them; and post-operatively in the case of patients already operated on with interventions based on the use of both the mammary arteries anastomosed with one another. If all or the major part of the by-passes in a patient receive a flow, for example from the mammary artery sx, a lesion at this level could result in very serious ischemia. Therefore, since a conventional direct infusion catheter could cause serious damage to the vessel, normally in such patients post-operative checks are not carried out unless there are serious signs of post-operative ischemia (also for

medico-legal reasons).

By means of the catheter described, a non-invasive diagnostic investigation can be carried out with contrast fluid, even on the mammary artery, which may advantageously be anastomosed for example with coronary vessels or with sections of saphenous vein.

Advantageously, the catheter described may be used selectively and non-traumatically for infusing any type of substance in the blood vessels, without the risk of causing lesions thereto and without producing useless dispersions of the substance injected.

In fact, the catheter described makes it possible to channel a flow of substance directly into the preselected vessel, avoiding dispersing same into other branchings.

The occluding body is further advantageously made of a material suitable for being subjected to sterilization treatment, for example a metallic or ceramic material, so that it can be sterilized according to known methods and re-used several times with different catheters.

Moreover, the combined occluding effect of the first and second occluding means facilitates the operation of occlusion of the distal end of the catheter. In particular, by inflating the balloon, the effect obtained is also a partial restriction of the calibre of the main cavity of the catheter, so that it is possible to use

occluding bodies having dimensions smaller than said calibre. In this way the insertion of the occluding body into the cavity is facilitated, avoiding the risk of the occurrence of any jamming thereof in the phase of insertion into the main cavity.

The tapered profile, for example frustoconical, of the distal end, since it restricts the calibre of the main aperture, makes it possible to use occluding bodies of dimensions smaller than the median calibre of the main cavity and therefore does not require particularly narrow tolerances for the calibre itself. The substantially hermetic closure of the main cavity is ensured by the contact surface between the occluding body and the distal end which is advantageously a limited contact surface, for example, circumferential for a spherical occluding body or frustoconical for a frustoconical or rhomboidal occluding body. Moreover, owing to the tapered profile, an end of travel of the occluding body is guaranteed and a relatively high specific contact pressure between the occluding body and the distal end, so as to guarantee the substantially hermetic closure of the distal end.

Advantageously, the costs of production of the catheter are significantly reduced in so far as, since a clearance is allowed between the occluding body and the main cavity, particularly narrow tolerances are not

required on the calibre of the main cavity.

An expert in the field, for the purpose of fulfilling contingent and specific requirements, may apply numerous modifications and variants to the catheter described above, all however contained within the scope of the invention as defined by the following claims.